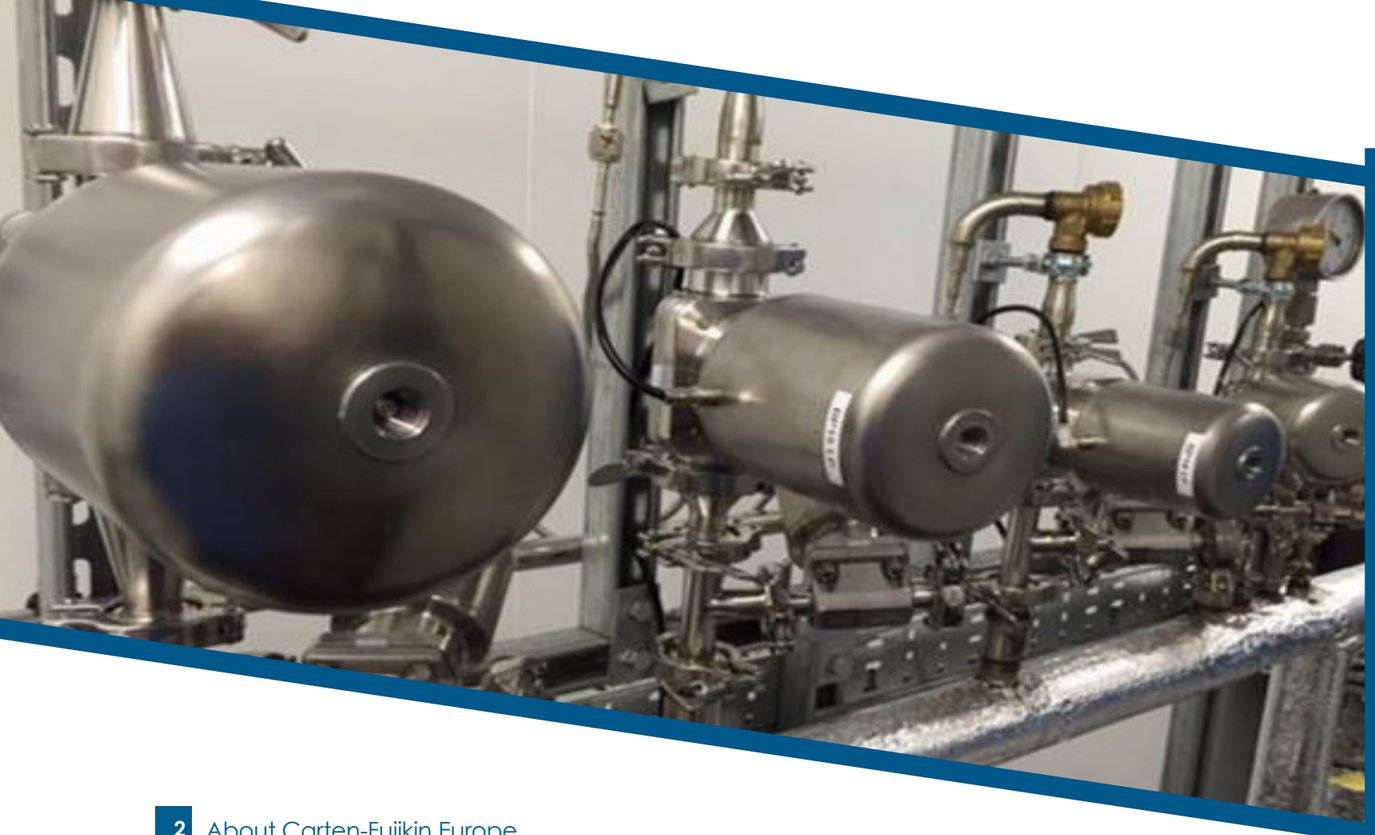
CARTEN®

High Performance Valves & Flow Solutions

BNW Series Weir Diaphragm Valves

Sterile, Aseptic and Sanitary Valves for Critical Process Systems

For Biotechnological, Pharmaceutical, Food and Beverage Process Systems



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About Carten-Fujikin Europe

Fujikin (FCG) are global leaders in the design, manufacture and development of High Performance Valves and Flow Solutions to high technology and demanding process sectors including Semiconductor, Photovoltaic, LED, Biotech, Pharmaceutical, Food & Beverage, PCI, Energy and Laboratory industries delivering products with safety, reliability, efficiency and performance to critical process systems and modules.

Fujikin have been supplying valves, fittings and piping products to industry since its inception in 1930. Understanding customer processes and requirements has driven FCG to innovate and develop leading edge performance valves, mass flow controllers, seal fittings and flow systems which deliver best-in-class performance, reliability and efficiency for its customers.

Carten valves are utilised globally in a wide variety of applications and systems in the most demanding industries. These include bulk gas delivery, lateral distribution systems, filter-skids, purifiers, valve manifold boxes (VMBs), valve manifold panels (VMPs), gas panel, solvent, hook-up and gas cabinet applications.
Together with Fujikin, Carten design and manufacture customised media flow solutions by utilising products from Carten-Fujikin's global network that deliver efficiency, reliability, safety and performance to specification and global standards.

Carten has grown considerably and is firmly established as a leading and innovative valve supplier to blue-chip global customers in the semiconductor, LED, photovoltaic and LCD markets. Our commitment to our customers and quality is demonstrated through our on-going membership and certification to the IS EN ISO9001 standard and PED certification by the implementation of continuous improvement initiatives throughout the company.

Carten-Fujikin has developed an optimal valve and sealing design to increase performance, durability and efficiency for demanding Biotech, Pharmaceutical, Food & Beverage process systems where purity, hygienic and sterile conditions are essential for product yield. The BNW series weir soft-seal diaphragm valves are available in 2-Way, 3-Way and Multi-Port configurations with tube stub and clamp end connections. The BNW series is available with a primary PTFE diaphragm combined with an EPDM reinforcement diaphragm and a one piece EPDM diaphragm option. The innovative deep drawn actuator top works for manual and pneumatic versions facilitates a light weight and ergonomic valve product suitable for bioreactors, fermenters, buffer vessels, process distribution, chromatography skids and centrifuge skids. Carten-Fujikin's BNW series diaphragm valves provide the lowest total cost of ownership (TCO) for end-users, equipment makers and system owners through reduced retorquing and minimal diaphragm replacement.

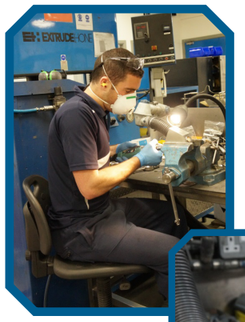
The company have expanded in line with industry demands and have invested heavily in new production capabilities. These include CNC machining, surface finishing, welding, electropolishing and high specification cleanrooms to ISO4, ISO5 and ISO6 standards.

Carten Controls' core product line includes high-purity bellows, diaphragm, check and ball valves and pharmaceutical diaphragm valves. We manufacture gas-pressure regulator's, dual-containment valves, vacuum generators, and ceramic and control valves in our state-of-the-art facilities in Ireland and the USA.

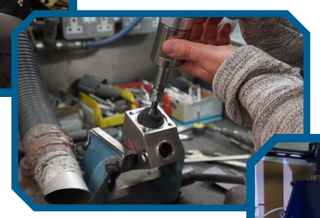
Organisational Capabilities

Carten Controls was founded in 1970 and in 1981 established its European operations in Waterford, Ireland. Understanding customer processes and requirements has driven FCG to innovate and develop leading edge performance valves, mass flow controllers, seal fittings and flow systems which deliver best-in-class performance, reliability and efficiency for its customers.

The Waterford facility is encompassing of an 8,000m2 site (3,901m2 production space) where ultra high purity and high performance valves and flow solutions are designed and manufactured on site utilising the following Equipment and Instrumentation:



- 18.2 Ω DI Water Generation Plant, with 18.2 Ω Purified Water System supply to all processes (ASTM D5127, USP 23)
- Electropolish, Passivation, and Effluent Treatment Plants to ASTM A380-A967-B912-EPA Standards
- 7 x Centrifugal Autogenous Tig Welding (GTAW) Lathes
- Manual Mechanical Polishing and 1 x Abrasive Flow Machines



- Automated Multi-Stage Hilsonic Aqueous Clean Line with Ultra Sonic and DI Water Rinsing
- Full CNC Machine Shop Capabilities Comprising CNC Milling/Lathe, automated cutting, and Toolroom for Jigging and Fixturing (2 x Toolmakers)

- Hydrostatic Test Capability as per ANSI FCI 70/2, Class IV & VI
- 6 x Mass Spectrometer Helium Leak Detectors

- 2 x PMS Lasair11 Particle Counter 0.1µm Detection Limit
- 1 x Naneum NPC10 Nano Particle Counter 0.01µm Detection Limit
- 1 x Halo Tiger Optics Moisture CRDS Trace Gas Analyser 2ppb Detection Limit
- 1 x Teledyne Oxygen Trace Gas Analyser 10ppb Detection Limit
- 1 x ATEQ F-Class Pressure Decay Leak Detector
- 1 x AMI207 ARC Orbital Weld Station
- 3 x AMI307 ARC Orbital Weld Station
- 2 x Tritool Severmaster AC Tube Cutters, with Squaring Modules
- 1 x Carbolite UHP (5.0 purity) Nitrogen Convection Oven
- 1 x Entegris Gatekeeper Gas Purifier Panel (<1ppb, 9.0 purity – process gases)
- UHP (5.0 purity) Nitrogen Process Gas Supply, Filtered to 0.025µm
- UHP (5.0 purity) Helium Process Gas Supply, Filtered to 0.025µm
- UHP (5.0 purity) Argon Process Gas Supply, Filtered to 0.025µm
- Extreme Clean Dry Air Process Gas Supply, Filtered to 0.025µm
- Automated Vacuum Packaging

Carten's SIP TEST RIG

A Key Feature in Carten's Research and Development Centre

With this SIP rig, Carten has the ability to carry out Steam in Place processes in accordance with customer requirements and specifications. This involves testing the sealing structure of the diaphragm in our own BNW Series diaphragm valves. Through this process the media, the cycle number and deviation can be independently stipulated.

Carten have invested in this SIP system for two primary reasons:

1. To determine the lifecycle of our PTFE and EPDM diaphragms to test the quality and to validate new developments and advancements in our materials against previous specifications.
2. To ensure Carten are equipped to accommodate for our customers specifications Carten have designed this steam rig with capabilities to carry out unique test cycles and procedures for individual customer requirements.

The steam generation rig relating to this procedure generates clean steam from water treated through reverse osmosis, complying with the definition of clean steam as defined by ASME BPE. ASME BPE (2014), Non-Mandatory Appendix J, Standard Process Test Conditions (SPTC) for Seal Performance Evaluation, J-1.2.1 Simulated Steam-in-Place (SIP) Testing (c) states "Steam-in-Place. Expose the system to a simulated SIP with saturated USP Pure Steam or equivalent (e.g. Steam generated from DI/RO water or equivalent)".

Potable water is treated through a water softener, directly followed by a reverse osmosis process. Reverse Osmosis (RO) works by utilising high pressure to increase the pressure on the unpurified side of the RO unit, forcing the water across a semi-permeable RO membrane, leaving almost all minerals behind in the reject stream. The water that is demineralised is called permeate (or product) water. The water stream that carries the concentrated contaminants that did not pass through the RO membrane is called the reject (or concentrate) stream.

The RO waters supplies a feed-water tank, which holds RO water for supply to an electric boiler – which is constantly supplemented by returned clean steam condensate to maintain as much efficiency in the steam generation process as is possible. The 36kW boiler generates a maximum saturated steam pressure of 10 BAR, or 184.2°C. As saturated steam is pressure dependent, a pressure-reducing steam regulator is utilised to control the temperature of clean steam to the test manifold (see Steam PRV, Figure 1). Temperature and pressure sensors are installed at the test manifold supply to ensure the correct parameters are set at this critical process input stage.

Why Choose the Fujikin BNW Series?

Carten-Fujikin has developed an optimal valve and sealing design to increase performance, durability and efficiency for demanding Biotech, Pharmaceutical, Food & Beverage process systems where purity, hygienic and sterile conditions are essential for product yield. The BNW series weir soft-seal diaphragm valves are available in 2-Way, 3-Way and Multi-Port configurations with tube stub and clamp end connections. The BNW series is available in three distinctive options; a manual version available with stainless steel or polymer handwheels, a standard pneumatic stainless steel version, and a high performance pneumatic stainless steel version. All versions come with both primary PTFE diaphragm and one piece EPDM diaphragm options. The innovative thin wall deep drawn formed actuator top works for manual and pneumatic versions facilitates a light weight and ergonomic valve product suitable for bioreactors, fermenters, buffer vessels, process distribution, chromatography skids and centrifuge skids.

Carten-Fujikin's BNW series diaphragm valves provide the lowest total cost of ownership (TCO) for end-users, equipment makers and system owners through reduced retorquing and minimal diaphragm replacement.

Carten-Fujikin's BNW series soft-seal weir diaphragm valve provides the most efficient and best-in-class total cost of ownership (TCO) for mission critical sterile processes. Key product features include:

- → ASME BPE Compliant Design and Dimensions
- → SIP500 Rated Life Durability (ASME BPE rating)
- → No Re-torquing Required
- → Compact and Light Weight Deep Drawn Stainless Steel Top Works
- → Wide Range of Operating Conditions
- → Reduced Polymer Cold Flow Sealing Design
- → Reduced Total Cost of Ownership for Process Systems
- → Electropolished Internal Surface
- → Primary PTFE Diaphragm with EPDM Back Up
- → One Piece EPDM Diaphragm Option
- → Excellent Drainability
- → 316L Stainless Steel Forged Valve Body
- → Resin Manual Handle Option
- → Range of Instrumentation Available
- → Conventional 2-Way Hygienic Clamp or Butt Weld End
- → 3-Way Zero Dead T (ZDT) leg configurations
- → Rated to 150°C (302°F)
- → SIP & CIP Capability
- → High Performance Option

Typical Applications

- Chromotography
- Purified Water Generation (WFI)
- SIP/CIP Utilities
- Cell Culture
- Cell Harvest
- Filtration

Technical Overview

Nominal Size	DN8	DN15	DN20	DN25	DN40	DN50
End Connections	Buttweld or Triclamp					
Body Material	SUSF316L (S31603)					
Bonnet Material	CF3M (S31603).					
Diaphragm Material	Modified PTFE/EPDM (Back up Rubber) or EPDM					
Pressure Rating	10 Bar CWP150 (150psi)					
Operating Temperature Range	-5 to 150°C (23 to 302°F)					
Surfach Finish	SF1-SF6					
Operating Modes	Standard Pneumatic, High Performance Pneumatic and Manual					

Diaphragm Material	Steam	Liquid Media	
		Min	Max
Modified PTFE/EPDM	Constant 150°C (302°F)	-10	90
EPDM	Constant 150°C (302°F)	-10	90

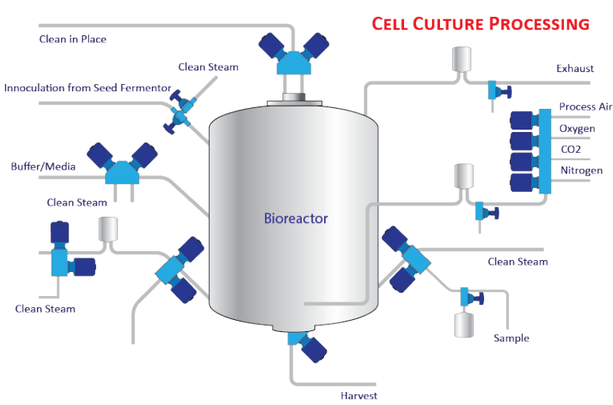
Port Connection		Kv-Value Water [m^3/h]		Cv-Value		Max. Operating Pressure				Drain Angle
						ΔP= 100%		ΔP= 0%		
[mm]	[inch]	PTFE	EPDM	PTFE	EPDM	High Performance Model	Standard BPE Model	High Performance Model	Standard BPE Model	
8	1/2"	2.4	1.8	2.8	2.1	10 Bar	6 Bar	6 Bar	3 Bar	22°
20	3/4"	5.4	3.4	6.2	4.0	10 Bar	6 Bar	6 Bar	3 Bar	16°
25	1"	11.2	9.4	13.1	11.0	10 Bar	6 Bar	6 Bar	3 Bar	22°
40	1 1/2"	23.3	18.3	27.1	21.3	10 Bar	6 Bar	6 Bar	3 Bar	18°
50	2"	43.2	40.6	50.2	47.2	10 Bar	6 Bar	6 Bar	3 Bar	16°

Typical Applications

Cell Harvest

After cell culture fermentation is complete the bioreactor is full of a cell culture medium which contains both the host cell and the target molecule. The location of the target molecule will determine subsequent processing requirements. Depending on the cell type used (mammalian vs. bacterial) the target protein will be contained within the cell (bacterial - intracellular) or expressed through the cell membrane into the cell culture solution (mammalian - extracellular). Extracellular product is excreted straight into the bioreactor broth, and usually harvested using centrifugation or TFF.
Intracellular requires cell lysis to release the target molecule – this typically requires homogenisation. Protein requires the outer cell wall to be disrupted, followed by centrifugation or TFF.

Cell Culture

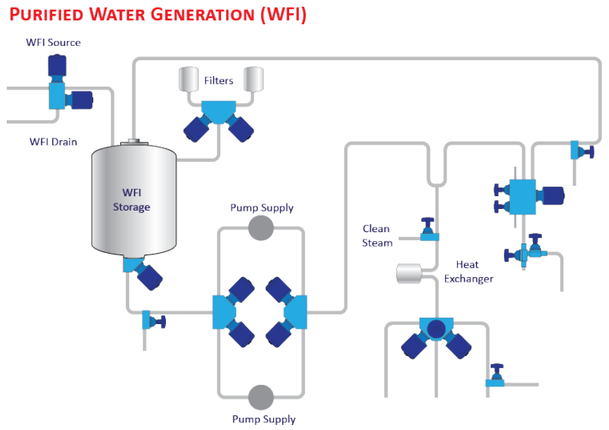


Produces a controlled environment where cell culture processing can take place under controlled conditions.
Cell culture processing is the growth and development of a cell line to produce a specific protein product for the benefit of patients.
The term Bioreactor is usually used for Cell Culture Processing associated with mammalian cell lines.
The term Fermenter is usually used for Fermentation Processing associated with microbial cell lines.
The growth rates for mammalian cell lines is quite slow (doubling every 24 hours), whereas microbial growth rates are much faster (20 minutes). To facilitate the growth rate of microbial lines, greater OTR is required. The expression of mammalian cell lines however is far more complex culturing process given the slower growth rates, higher sensitivity to pH, and higher sensitivity to thermal exposure.

SIP/CIP Utilities

Clean-In-Place (CIP) chemicals are utilised to remove contaminants from product contact surfaces post drug batch production. The chemicals and temperature utilised depends on the product and process layout, but a general rule is a minimum velocity of 1.52m/s must be achieved. Inorganic media contaminants (salts, sugars, starches) will generally require an acidic cleaning agent such as phosphoric acid, whereas organic contaminants (fatty acids, blood, proteins, fats) require an alkali cleaning agent such as sodium hypochlorite or sodium hydroxide. Water soluble waste is best cleaned with water.

Steam-In-Place (SIP) saturated steam is the method of choice at a minimum temperature of 121°C, also used for autoclaving. UHT and HTST higher temperature cycles are becoming more common to ensure sterilisation is achieved in shorter time periods. Dead legs, entrapments zones, and correct flow paths are critical to maintaining a sterile zone. All component design must be compatible (bioreactor, valve, seals) with both the high temperature achieved during sterilisation, and the thermal cycle that can create hugely damaging alternating conditions for equipment. The correct treatment of condensate, and the elimination of air from zones to be sterilised is critical.



Purified Water Generation

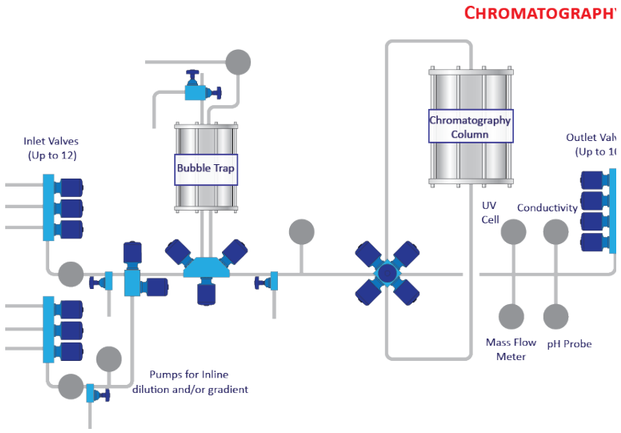
Water for Injections (WFI) is used to make both fermentation media and culture media for cell lines, and any parenteral drugs. In addition it is utilised exclusively in all downstream biopharmaceutical processing procedures. It must ensure a low endotoxin content, and low initial bioburden to enable sterilisation by filtration to become a more straightforward task. Generally chromatography (IEX) and reverse osmosis (RO) is utilised to ensure an appropriate level of purity.

Filtration

This method of separation is based almost uniquely on the size difference between the target molecules intended to separate.
Filtration is defined as the process in which particles are separated from a liquid by passing the liquid through a permeable medium. The porous filter medium is the permeable material that separates particles from the liquid passing through it and is known as a filter element. The two main filtration methods are normal flow filtration (NFF) and cross-flow or tangential flow filtration (TFF).
The advantage of cross-flow filtration as compared to normal flow is that you can pass much greater process volumes through the same membrane area. This is due to material being swept across the filter surface in a tangential mode producing far less build-up of cake or gel layers on the surface – so greater filter performance over time. Another advantage of tangential flow filtration membranes is that the filters can be cleaned and reused.

Chromatography

Chromatography contains a mobile and stationary phase, exploiting differences between both to separate proteins from the media. The product stream is passed through the stationary phase and depending on the condition of the mobile phase and the interaction with the surface of the stationary phase, molecules will spend a different amount of time present between the two phases.



Polarity (NPLC/RPLC), charge (IEX), biologic affinity (affinity chromatography), and size (SEC/Gel Filtration) are some of the methodologies used to separate protein. At this stage of the process, volumes are reduced as contaminates are eliminated and the purity is increased dramatically. The strategy of Capture, Intermediate Purification and Polishing (C.IP.P) is used to develop a multi-step purification process.

Advantages of the BNW Series

1 ASME BPE Quality and Compliance

The ASME BPE standard drives the requirements applicable to the design of equipment used in the biotech, pharmaceutical and healthcare industries, as well as other applications with high levels of hygienic and sterile requirements. Carten-Fujikin's BNW weir soft-seal diaphragm valve complies with the design and performance standards demanded for high process performance systems facilitating high yield, high productivity process environments with reduced down time for maintenance, reduced diaphragm replacement, standard ASME dimensions and high quality surface finish in product contact systems and equipment. Carten-Fujikin's production system delivers consistent and repeatable valve performance with the Quality Management System and product control and traceability through the manufacturing process.

2 Technological Advantage

The BNW seal design developed by Carten-Fujikin removes the EPDM back up diaphragm from the sealing surface. This reduces 'cold flow' as EPDM deforms to a far greater degree than PTFE under significant and constant load – as a diaphragm seal is when torqued, therefore eliminating the different expansion & contraction rates of two different polymers during the thermal cycling process, even at elevated temperatures during typical HTST cycling. A location bead allows ease of maintenance, eliminating any risk of misalignment of the diaphragm during scheduled replacement.

3 Traceability

Carten-Fujikin Europe ensures each and every diaphragm is traceable back to the material compound, material supplier, batch of production, and polymer cure date. As the line size, manufacturer identification, and product part code are also permanently marked onto the moulded diaphragm – compliance with both ASME BPE and MSS-SP-88 is assured. Each valve is individually serialised.

The 316L/1.4435 stainless steel forgings can similarly be traced back to the type of steel heat used, material supplier, batch of production, and product contact surface roughness. As the pressure-temperature rating, manufacturer, valve series, and line size are also permanently marked – compliance to ASME BPE and MSS-SP-88, and certification to the Pressure Equipment Directive Module D1 (Category 2) is realised.

4 Competitive Price and Performance

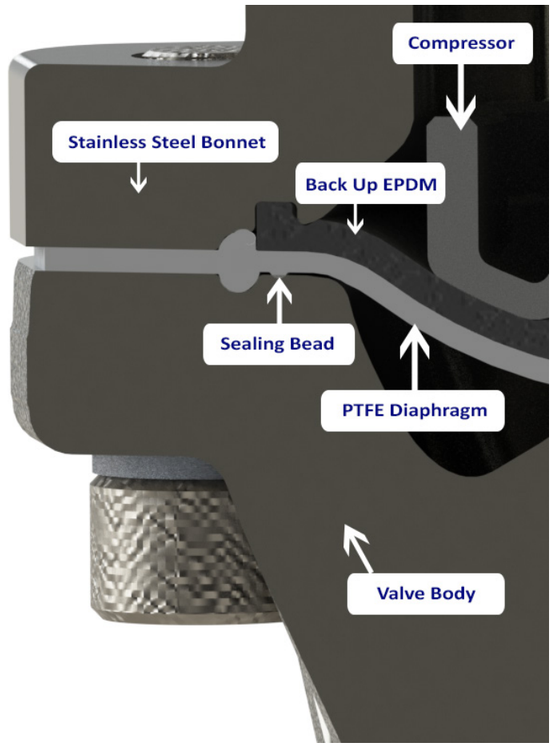
Carten-Fujikin provides the lowest total cost of ownership for its BNW weir soft-seal diaphragm valve product range. The BNW valve series provides a competitively priced product with the high performance capability demanded by the Biotech, Pharmaceutical, Food and Drink industries. Carten-Fujikin's quality and technical support ensures all customers receive efficient value and reliability in mission critical process systems.

5 Global Support

The FCG distribution network supports global supply of product through its distribution partners and direct global network. This enables fast time to market and responsiveness for customer product demands and delivery and post purchasing needs and customer support.

6 Diaphragms

Carten-Fujikin Europe performs a verification FTIR analysis for all diaphragm compounds to ensure exact conformance to known material spectra fingerprints. All diaphragms meets the minimum requirements of FDA CFR Title 21 177.2600 (elastomers) and 177.1550 (perfluorocarbons), and USP <87> <88> Class VI. A modified In Vivo analysis also includes analysis as per ISO10993, which is superseding the USP analysis.



7 Valve Modulisation/Constructability

Carten-Fujikin has designed numerous Multiport and block valve designs and modular systems for customers. The collaboration and expertise of Japanese and European valve design, robust and rigorous testing in severe environments ensures Carten-Fujikin's products are constructed to meet global standards and regulatory demands.

8 Test Centre

Carten-Fujikin Europe has constructed a state-of the-art test facility that allows the repetition of industrial installation condition, to ensure every valve is fit for purpose. In-house capabilities include Steam-In-Place thermal cycling capability to match ASME BPE and industry standards, replication of Clean-In-Place (CIP) flow, verification of valve drainability, and fluid control and leak integrity at Δ P=0% and Δ P=100% condition. Our in-house capability allows the reproduction of exact customer specification – tailored pressure profiles, installed slope, sterilisation temperature and duration, cooldown process parameters and more can be replicated to match installed condition to ensure confidence in all product.

9 Improved Servicability

The BNW series meets the requirements for ASME BPE SIP500 thermal cycling. As retorquing is reduced the necessity for serviceability is reduced also extending the durability and lifecycle of the valve, reducing on-site maintenance, reducing diaphragm replacement cycles, reducing downtime thus ensuring maximum productivity in critical process systems. The BNW Series reliability ensures reduced TCO for customers and system owners.

10 Engineering Support and Design

Carten-Fujikin supports its BNW soft-seal diaphragm valves through engineering services including modular design, flow analysis and calculations based on customer requests.

2-Way Diaphragm Valves

Standard ASME BPE Compliant Manual Valve

Bonnet		JIS SUSXM7 (S30430)
Handwheel		ASTM A351 CF8 (J92600) or PPS (Polyphenylene Sulphide)
Operating Pressure		0-10 BAR
Operating Temperature		0-150°C
Connection Type	Butt Weld End	•
	Tri-Clamp End	•
DN		8-50
Diaphragm Size	8	•
	15	•
	25	•
	40	•
	50	•

Standard ASME BPE Pneumatic Diaphragm Valve

Bonnet		ASTM A351 CF8 (J92600)
Cylinder		JIS SUSXM7 (S30430)
Operating Pressure	ΔP= 100%	6 BAR
	ΔP= 0%	3 BAR
Operating Temperature		0-150°C
Connection Type	Butt Weld End	•
	Tri-Clamp End	•
DN		8-50
Diaphragm Size	8	•
	15	•
	25	•
	40	•
	50	•

NEW

High Temperature High Performance Pneumatic Diaphragm Valves

500 THERMAL CYCLES

10 BAR

150°C

Carten offer a high performance pneumatic valve version, in addition to the standard BPE pneumatic model. The high performance version is compliant and validated to all ASME BPE thermal cycling specifications – achieving a minimum of 500 thermal cycles (500 SIP as per ASME BPE), but in addition has been validated using an accelerated high temperature validation protocol at a minimum of 150C, achieving a minimum of 100,000 valve cycles across all line sizes at this elevated temperature.

The high-thrust pneumatic actuator design allows operation in high pressure lines up to 10BAR, ensuring this valve specification is unique for bioprocessing and pharmaceutical markets. This high specification provides the end user the capability and reassurance to operate modern hygienic processes such as HTST sterilisation, in addition to a significant process parameter safety margin to suit their design space requirements.

100,000 CYCLES AT ELEVATED TEMPERATURE

Bonnet		ASTM A351 CF8 (J92600)
Cylinder		JIS SUSXM7 (S30430)
Operating Pressure	ΔP= 100%	10 BAR
	ΔP= 0%	6 BAR
Operating Temperature		0-150°C
Connection Type	Butt Weld End	•
	Tri-Clamp End	•
DN		8-50
Diaphragm Size	8	•
	15	•
	25	•
	40	•
	50	•

Custom Solutions

Carten has been designing, manufacturing and supplying ultra-high purity valves and flow solutions from its Waterford facility for over 30 years. The Carten BNW series weir soft-seal diaphragm valves are available in 2-Way, 3-Way, Tandem and Multi-Port configurations with tube stub and clamp end connections.

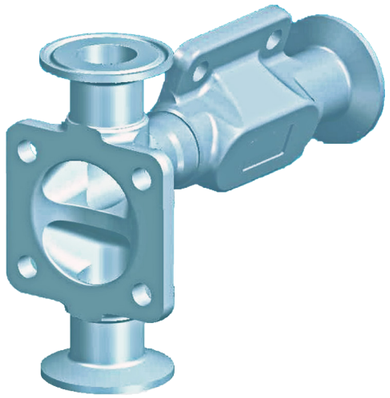
Carten's custom valve solutions are encompassing of offerings to the customer including conventional designs and 2 way solutions configured into welded tandem solutions, while also transforming these conventional offerings into multiport and block valves machined from solid block types or manifold options consisting of a combination of these technologies.

Our In-house engineering design team use computer simulation to illustrate fluid dynamics, dimensional specifications and 3D modelling. This along with Carten's in-house machine shop ensures that the mechanical integrity of each block valve or multiport design has limited dead space. To ensure customer satisfaction all Carten valves, manifold configurations and solutions are 100% leak tested before and after welding and electropolishing processes.

All valve components and block configurations are supplied with full certification and are fully traceable.
Carten-Fujikin ensures each and every component is traceable back to the material compound, material supplier, batch of production, and polymer cure date. As the line size, manufacturer identification, and product part code are also permanently marked onto the moulded diaphragm – compliance with both ASME BPE and MSS-SP-88 is assured. Each valve is individually serialised. The 316L/1.4435 stainless steel forgings can similarly be traced back to the type of steel heat used, material supplier, batch of production, and product contact surface roughness. As the pressure-temperature rating, manufacturer, valve series, and line size are also permanently marked – compliance to ASME BPE and MSS-SP-88, and certification to the Pressure Equipment Directive Module D1 (Category 2) is realised.

Carten have a sales and engineering team in place to work with customers on identifying the optimal solution for each unique piping system/task. For enquiries and customer support contact sales@cartencontrols.com

Tandem Valves



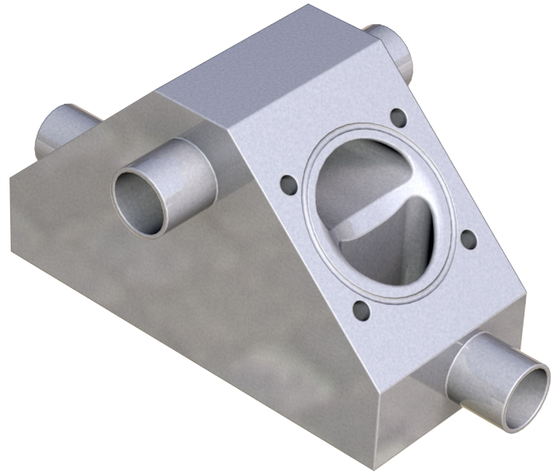
The first of Carten's customised valve solutions for our customers. Tandem valves are designed to optimise drainability while also minimising dead legs to meet process design specifications. For this design we usually weld an access valve to a main valve to create GMP or SAP configurations. All our tandem valves are supplied with full material certification.

Multiport and Block Valves

Carten-Fujikin has been developing innovative solutions to satisfy customer and industry requirements for many years. To do this successfully, Carten utilises 3D modelling to create our block designs and solutions.

Carten has dealt with numerous enquiries focusing on the minimalising of internal volume, reducing contact surface space internally in the valve, reducing the cycle time for CIP/SIP processes, and to decrease deadleg space in the valve. Each enquiry is unique to the customer and process and Carten-Fujikin explores multiple options to provide the best product and service.

Each request received is dealt with in strict confidence ensuring the customers process and specifications are secure at all times.

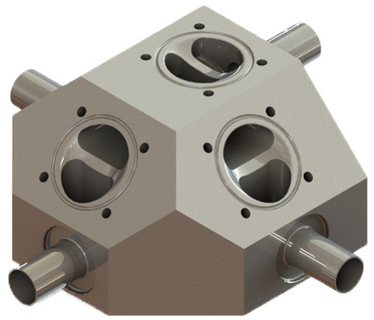


Cost Effective

Installation Time Reduced

There are many benefits in choosing a Carten-Fujikin multiport valve configuration. These include:

1. The reduction in process pipework footprint
2. Installation time minimized due to the compact block design
3. Cost effectiveness- the block solution can in many cases replace the necessity for up to 12 conventional valves, therefore reducing the overall cost for the customer.



Carten-Fujikin work closely with OEM's on providing the best solutions to the customer.

To design and manufacture customised block valves for Carten need to know a number of things. This includes standard details of the operating condition, pipe orientation and valve functionality and further details including valve size, number, connection type, block material and control type.

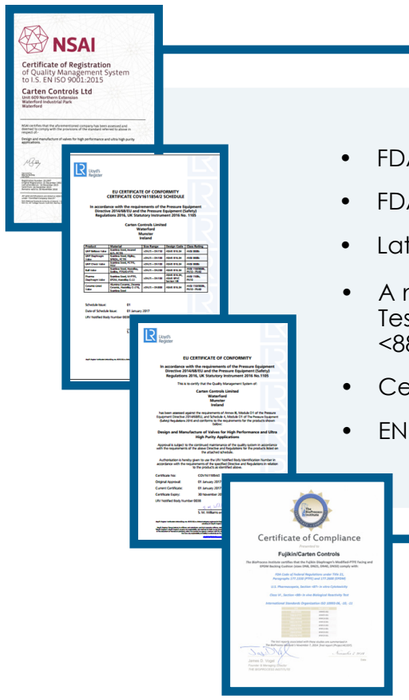
Once the above details are exchanged in early development stages Carten can design and manufacture an optimal solution for the customer.

Process Pipework

Footprint Reduced

Quality and Compliance

Carten's Biotech/Pharma Certification Summary



- FDA extraction per 21CFR177.2600 (Elastomers)
- FDA extraction per 21CFR177.1550 (PTFE)
- Latest Edition of the US Pharmacopea USP In Vitro Class VI <87>
- A modified Class VI protocol for In Vivo Biological Reactivity Testing that meets ISO and USP Class VI with histopathology - USP <88>/ISO 10993-6, -10 and -11.
- Certified as per the Pressure Equipment Directive 2014/68/EU
- EN 10204 3.1 Certified Materials

Carten In-House Capabilities

- Shadowgraph Profile Projector
- 3D Shadowgraph Profile Inspection
- Surface Profilometry
- Motic Ratio Stereomicroscope
- Borescope Analysis
- Kanban Pull System in Operation, controlled by internally developed VB software
- Computer Integrated Product Tracking System & ISO9001:2015/PED Module D1 Paperless QMS
- CE Marked (PED Compliant) for all Carten and Fujikin products
- ASME BPE compliant production for FCG soft-seal BNW valves
- Solidworks 3D Drawing Package
- Solidworks Computational Flow Dynamics and Finite Element Analysis to simulate media flow through valves and forces in design, R&D, test.
- Dedicated R&D centre for durability testing, flow testing, pressure testing, new product validation.
- Steam-in-place (SIP) thermal cycle test rig for FCG soft-seal weir and weirless diaphragm valves.
- Drainability analysis rig

ASME BPE Compliance

The ASME BPE standard drives the requirements applicable to the design of equipment used in the biotech, pharmaceutical and healthcare industries, as well as other applications with high levels of hygienic and sterile requirements. Carten-Fujikin's BNW weir soft-seal diaphragm valve complies with the design and performance standards demanded for high process performance systems facilitating high yield, high productivity process environments with reduced down time for maintenance, reduced diaphragm replacement, standard ASME dimensions and high quality surface finish in product contact systems and equipment. Carten-Fujikin's production system delivers consistent and repeatable valve performance with the Quality Management System and product control and traceability through the manufacturing process.

Biocompatibility

ASME BPE (Part PM-3.1) defines biocompatibility "as the ability of a substance or material to be in contact with living matter such as bacteria or mammalian cells without interfering in any way with its metabolism or ability to live and procreate", requiring that "polymer materials shall be biocompatible with the system fluid to ensure that the system fluid is not adversely affected by the polymer material". To ensure biocompatibility, a variety of laboratory testing must be completed to assure compliance with the relevant United States Food and Drugs Association (FDA), United States Pharmacopeia (USP), and International Standards Organisation (ISO) requirements.

As a basic first step, material verification of the polymer compound is assured. Fourier Transform Infrared Spectroscopy (FTIR) is an analytical technique used to identify chemical compounds in a polymer product through the absorbance of infrared light at different frequencies. This produces a unique spectral fingerprint specific to that class of material. All Carten-Fujlkin compounds are verified using this method. Traditionally the United States Pharmacopeia is utilised to assess biocompatibility. This includes In Vivo USP<88> requirements, incorporating the criteria for USP Class VI Testing, and an In Vitro USP <87> test requirement. To standardize biocompatibility testing on a global scale, the International Standards Organization (ISO) developed ISO 10993 – a twenty-part standard that evaluates the effects of medical device materials on the body. To ensure compliance with both ISO and USP requirements, a modified Class VI protocol for In Vivo Biological Reactivity Testing that meets ISO and USP Class VI with histopathology - USP <88>/ISO 10993-6, -10 and -11 is utilised for all Carten-Fujikin diaphragms.

Title 21 of the Code of Federal Regulations (21 CFR) is a nine volume set of regulations enforced by the FDA. Part 177 of Volume 3 of 21 CFR (21 CFR 177) describes polymers which are permitted as components of single and repeated use food contact surfaces. Part 177.1550 governs Perfluorocarbon Resins, specifying composition data & characteristics of the M-PTFE product contact diaphragm - whereas Part 177.2600 governs Rubber Articles Intended for Repeated Use, specifying composition data & characteristics of the EPDM product-contact or backing diaphragm.

BNW Series Product Description

BNW - TWV15A4 -1A20 - PE - MU

No.	Meaning	Description	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	Valve Series	BNW	BNW													
2	Body Configuration	Two Way Valve		TWV												
		Zero Dead Leg Tee		ZDT												
		Block Valve		BLK												
		Tandem GMP Orientation		TAG												
		Tandem SAP Orientation		TAS												
		Tandem TEE		TAT												
3	Body Size	8: DN8 1/4"			8											
		15: DN15 1/2"			15											
		25: DN25 1"			25											
		40: DN40 1 1/2"			40											
		50: DN50 2"			50											
4	Material of Body	A: ASTM A182 (Forging)				A										
		F: ASTM A479/A276 (Bar Stock)				F										
5	Surface Finish	SF1 (20µin/0.51µm)					1									
		MP SF2 (25µin/0.64µm)					2									
		SF3 (30µin/0.76µm)					3									
		SF4 (15µin/0.38µm)					4									
		EP SF5 (20µin/0.51µm)					5									
		SF6 (25µin/0.64µm)					6									
6	Connection Type	1: Tube						1								
		2: Clamp						2								
		3. Clamp (ASME BPE- EN558-1, Series 7)						3								
		4: Tube with Barb Sample Outlet						4								
		5: Tube x Clamp						5								
		6: FSM Female Connection						6								
		7: FSM Male Connection						7								
7	Connection Standard	JIS							J							
		ASME BPE- Tube/Clamp							A							
		EN10357- Series A | DIN 11850 Series 2							B							
		EN10357 - Series B | DIN 11850 Series 1							C							
		EN10357 - Series C | EN ISO 1127 (DIN 11866 Series B)							D							
		EN10357 - Series D | SMS 3008							E							
8	Connection Size	6: DN6 1/8"								6						
		8: DN8 1/4"								8						
		10: DN10 3/8"								10						
		15: DN15 1/2"								15						
		20: DN20 3/4"								20						
		25: DN25 1"								25						
		32: DN32 1 1/4"								32						
		40: DN40 1 1/2"								40						
		50: DN50 2"								50						
9	Diaphragm - Wetted Area	PTFE									P					
		EPDM									E					
10	Back Up Diaphragm	No Back Up										O				
		EPDM										E				
11	Control Type	Spring Return (N.C.); Low Pressure											C			
		Spring Return (N.C.); High Pressure											H			
		Manual											M			
12	Topworks Material	Stainless Steel												U		
		Resin (Plastic)												R		
		Stainless Coated Stem and Internal Bonnet												A		
		Resin Coated Stem and Internal Bonnet												B		
13	Instrument Options	(Available on Request)														
14	Additional Requirements															

Application Specification Sheet

Inquiry Ref # _____ Client: _____

Tag # _____ Project: _____

P & ID # _____ Location: _____

Date: _____

Application/ Operation	Service	Application Detail		Normal Operating Temperature °C or °F	Operating Low Temperature °C or °F	(High) Design Temperature °C or °F	Normal Operating Pressure (psig or bar)	High Design Pressure (psig or bar)	Shut Off Pressure (0%/100%) ΔP	Cycle Frequency per day/week/ year	Duration
	Size										
	Rupture Disk Set Pressure	Pressure _____ psi									
		Service Descriptions	Concentration %								
	Process Fluid										
Steam	Continuous □Yes □No Intermittant □Yes □ No										
Purified Water/WPI	□Yes □ No										
Other	□Yes □ No										
CIP	Sodium Hydroxide □Yes □ No										
	Phosphoric Acid □Yes □ No										
	Sodium Hypochlorite □Yes □ No										
	Other □Yes □ No										
SIP	□Yes □ No										
Autoclave	□Yes □ No										
Passivation	Check one:										
	Citric Acid □Yes □ No		Concentration ___%								
	Nitric Acid □Yes □ No		Concentration ___%								
	Phosphoric Acid □Yes □ No		Concentration ___%								
	Other □Yes □ No		Concentration ___%								
Solids	□Yes □ No		Concentration ___%								
Valve Operation											
Mode of Operation: Valves	Manual □Yes □ No			Diaphragm material currently using? (Please state in the space below)							
	Automated □Yes □ No	Min. Air Pressure _____ psi or bar Max. Air Pressure _____ psi or bar									

CARTEN–Fujikin

High Performance Valves and Flow Solutions

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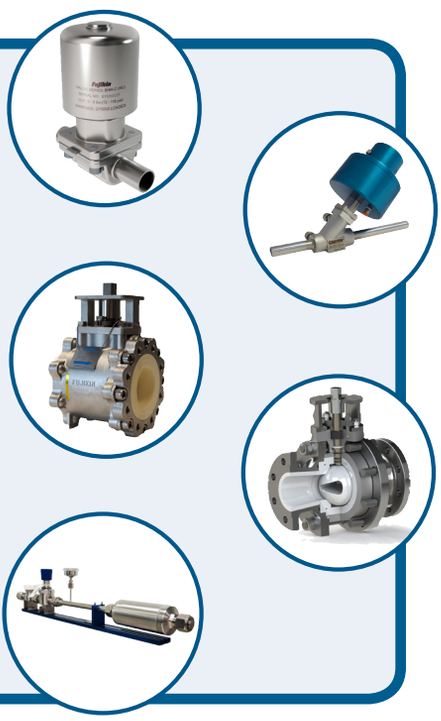
Carten Controls and Fujikin Deutschland are members of the Fujikin Carp Group (FCG) with Headquarters in Osaka Japan.

The Carten-Fujikin Range



- Bellows Valves
- Ball Valves
- Check Valves
- Diaphragm Valves
- Tank Valves
- Sampling Valves
- Hybrid Single Use Pinch Valves
- Ceramic Valves
- Integrated Gas Sticks and Systems